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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/524,101	03/13/00	BUCHMAN A	EX00-015

EXAMINER	
DHRUVA, B	
ART UNIT	**PAPER NUMBER**
1632	5

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HM12/0620

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/524,101	BUCHMAN ET AL.	
	Examiner	Art Unit	
	Bharati R. Dhruva	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-28* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Notice to Comply

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 . A paper copy of the "seqeunces listing" is not submitted as required by 37 C.F.R. § 1.821(c) and a copy of the "seqeunces listing" in computer readable form has not been submitted as required by 37 C.F.R. § 1.821(e). Applicant must provide a paper copy and a computer readable form (CRF) copy of the "seqeunce listing" and a statement that the content of the paper and computer readable copies are same and include no new amtter as required by 37 C.F.R. § 1.821(e), (f) or (g) or 1.825 9b) or (d).

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-13, are drawn to an isolated nucleic acid molecule classified in class 536 subclass 23.1 and 25.1

II. Claims 14-16 is drawn to polypeptide classified in class 530 subclass 300.

III. Claim17-21 drawn to method of detecting compound or molecule that modulates p53 activity classified in class 435 subclass 6 & 7.1

IV. Claims 22-26 are drawn to genetically modified insect and a method of studying p53 activity by detecting phenotypic changes in a genetically modified insect classified in class 800 subclass 13

V. Claims 27-28 drawn to a method of modulating p53 activity by using RNA classified in class 536 subclass 25.1

The inventions are distinct, each from the other because of the following reasons:

Inventions of group I and groups II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the nucleic acid of group I have separate and distinct chemical entity than the group II peptides. Furthermore, the group I invention nucleic acid can be used as a hybridization probe or for production of protein and group II can be used for production of antibody or as a therapeutic agent.

Inventions of group I and group III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions group I invention is a chemical and group III is a method of detection and has different ingredients, method steps and endpoints. Furthermore the invention of group I can be used as a hybridization probe or for production of protein.

Inventions group I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the group I nucleic acid is chemical with distinct biochemical and biophysical properties while group IV is an assay using transgenic insects.

Inventions group I and group V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid of group I, in addition to being used in the method of group VI can be used for production of protein or as hybridization probe. Hence the invention are distinct.

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein of group II, in addition to the method of group III, can be used as an antigen for producing antibody. Hence the inventions are distinct.

Inventions group II and IV-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different

modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the group II invention is polypeptide and group IV, is an assay using transgenic insects which has different ingredients, method steps and endpoint. Furthermore the assay does not require the peptide of group II. Group V method of modulating p53 activity has different method steps, ingredients and endpoints. Furthermore it does not require the peptide of group II. Hence the inventions are different.

Inventions group III, V ,VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are different methods, method of detecting compound that modulate p53 activity, method of studying p53 activity and method of modulating p53 activity. They differ with respect to ingredients, method steps and endpoint: therefore each method is patentably separate.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

Applicant must select one of the SEQ ID NOS: 2,4,6,8,10, 20,22 **and** one of the SEQ ID NOS: 1,3,5,18.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Bharati R. Dhruva whose telephone number is (703) - 605-1157. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Schwartzman can be reached on (703) 308-7307. The fax phone

numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and for After Final communications.

Question of formal matters can be directed to the patent analyst Phillips Williams, whose phone number is (703) 305-3482.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0196.

BRD

June 13, 2001

ROBERT A. SCHWARTZMAN
PRIMARY EXAMINER